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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/336,259 | 06/18/1999 | JINDRICK KOPECEK | T6425NP | 7422 |

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| EXAMINER |
| GUPTA, ANISH |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1654 | |

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/336,259 | KOPECEK ET AL. |
| | Examiner Anish Gupta | Art Unit 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 2-6,9,11,19,20,22-26,29,31,39 and 40 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,7,8,10,13-18,21,27,28,30-38 and 41-44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Election/Restrictions

1. Applicant's election with traverse of the species HPMA, DAMA and proteins having coil-coiled structures as protein domain and insulin as the bioactive agent is acknowledged. The traversal is on the ground(s) that there is no undue burden that is placed on the examiner to examine all listed species because of the commonality of the dominant elements in the claims, presumably the cross-linking of hydrogels with protein domains. This is not found persuasive because the claims have to be searched based on the individualized structures. The claims recite species that are structurally distinct from one another. A search for HPMA, for example, would not lead to a result of DAMA. Thus, the search would be burdensome since each structure would have to be searched.

The requirement is still deemed proper and is therefore made FINAL.

A search was conducted for the elected species of HPMA, DAMA, coiled coil protein as the protein domain and insulin. No prior art was found on the elected species and held to be allowable. The search was then extended to the Markush group. Art was found on the species of polyethylene oxide crosslinked with a protein. Claims 1, 7, 15-18, 21, 27, 35-38, 41-44 read on the elected species. Claims 8, 10, 12, 13, 14, 28, 30, 32, 33, and 34 are free of prior art but subject to 11w First paragraph below. Claims 2-6, 9, 11, 19-20, 22-26, 29, 31, 39-40 are withdrawn from consideration as corresponding to non-elected species.

To expedite prosecution, all of the claims have been examined with respect to 112 First and Second Paragraph issue. Rejections based on these requirements are cited below for claims 1-44. However, claims 2-6, 9, 11, 19-20, 22-26, 29, 31, 39-40 withdrawn from consideration because the claims have not been examined for art purposes. In the event these claims were subject to

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examination, a 112 First paragraph rejection would be made on the claims as cited below. For this reason, these claims have been included in the 112 Rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 7, 15-18, 21, 27, 35-38, 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Fortier (US 5733563).

The claims are drawn to a composition for preparing a hybrid hydrogel.

The reference discloses polyethylene oxide cross-linked with albumin to produce a hydrogel (see col. 4, lines 18-30). The cross-linking is done with covalent linkage (see col. 6, lines 28-30). The reference therefore meet the limitations of the claims.

Specification

The disclosure is objected to because of the following informalities: The provisional application cited in the first sentence of the application is incorrect. The application should be 60/089,862 instead of 60/089,062.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a composition for preparing stimuli responsive hybrid hydrogel. However, it is unclear, from the claim if the composition is the cross-linked product or just the constituents involved to create the hybrid hydrogel. The claim as currently written implies that the hydrogel comprises the polymeric network consisting of the cross-linked product and not the composition for comparing.

In claims 10-14 and 30-34 the claims recite “derivatives of.” However, it is unclear as the modification necessary in the compound to render it a “derivative.” Since one does not know if a particular modification is a “derivative,” the claims are therefore indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 and 9-27 and 29-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . ."). Regents of the University of

California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to formulation comprising a water soluble polymer or derivatives thereof and a protein domain. The generic statements water soluble polymer or derivatives thereof and protein domain does not provide ample written description for the compounds since the claims do not describe a single structural feature. Further, the statements regarding bonding interaction does not sufficiently provide ample written description since this only describes the presence a conjugation linkage, i.e a non-covalent linkage. The specification does provide examples of what qualify as compounds of the claimed invention. However, the peptides are limited to fusion protein containing a homo-dimeric coiled-coil domain, such as EK42 fusion protein.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claims are a broad

generic with respect all possible compounds which are polymer derivatives and protein domains.

The possible structural variations are limitless to any class of polymer so long as it is water-soluble.

It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. That is, one of ordinary skill in the art could not visualize a structure based on the functional characteristics alone, i.e. water-soluble polymer and protein domain.

Moreover, the specification lacks sufficient variety of species to reflect the variance in the genus since the specification does not provide any examples of derivatives. The specification is limited to the above mentioned fusion protein containing a homo-dimeric coiled coil structure. There is no disclosure of a proteins beyond these coiled-coiled fusion proteins that could be used within the context of the claims. Moreover, the specification does not provide ample description of modifications to polymers that render the polymers derivatives. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (571) 272-0961. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta 4/16/04
Patent Examiner